

AMENDMENTS

IN THE CLAIMS

1. (canceled)
2. (previously presented) A stable pharmaceutical formulation comprising an effective amount of torsemide modification II and a pharmaceutically acceptable excipient wherein the excipient has a low moisture content.
3. (previously presented) The stable pharmaceutical formulation of claim 2, wherein the excipient having a low moisture content is selected from the group consisting of lactose anhydrous, crospovidone, povidone, microcrystalline cellulose, and magnesium stearate.
4. (original) The stable pharmaceutical formulation of claim 2 comprising torsemide modification II in an amount of about 2.5 mg to about 200 mg per tablet.
5. (original) The stable pharmaceutical formulation of claim 4 comprises torsemide modification II in an amount of about 2.5 mg, about 5 mg, about 10 mg, about 20 mg or about 100 mg per tablet.
6. (previously presented) A stable pharmaceutical formulation comprising an effective amount of torsemide modification II wherein no more than 15% of the torsemide modification II rearrange into another form of torsemide during storage under stress conditions for at least 3 months, wherein the stress conditions are about 40°C and about 75% relative humidity.
- 7-8. (canceled)
9. (previously presented) A stable pharmaceutical formulation comprising an effective amount of torsemide modification II wherein no more than 15% of the torsemide modification II

rearrange into torsemide modification I upon storage under stress conditions for at least 3 months, wherein the stress conditions are about 40°C and about 75% relative humidity.

10. (original) The stable pharmaceutical formulation of claim 9 wherein not more than 5% of the torsemide modification II rearranges into torsemide modification I.

11. (previously presented) The stable pharmaceutical formulation of claim 6 wherein the torsemide modification II is selected from the group consisting of high purity torsemide modification II and torsemide modification II containing torsemide modification I at trace amounts, wherein the high purity torsemide modification II contains less than about 0.5 weight% torsemide modification I, and wherein the trace amounts of torsemide modification I is about 0.5 weight% to about 2 weight%.

12. (previously presented) The stable pharmaceutical formulation of claim 11 wherein the torsemide modification II is torsemide modification II containing torsemide modification I at trace amounts.

13. (original) The stable pharmaceutical formulation of claim 6 wherein the torsemide modification II has a particle size distribution such that 100 % is below 200 μ .

14. (original) The stable pharmaceutical formulation of claim 13 wherein the particle size distribution is such that 100% is below 100 μ .

15. (original) The stable pharmaceutical formulation of claim 14 wherein the particle size distribution is such that 100% is below 50 μ .

16-49. (canceled)

50. (previously presented) The stable pharmaceutical formulation of claim 11, the torsemide modification II containing torsemide modification I at trace amounts, wherein the trace amounts is about 0.5 weight% to about 2 weight%, and wherein the formulation further comprises a

combination of excipients selected from lactose anhydrous NF, crospovidone NF, povidone USP and microcrystalline cellulose NF.

51. (previously presented) The stable pharmaceutical formulation of claim 50, containing a moisture content of 0.5-1.5%.

52. (previously presented) A stable pharmaceutical formulation comprising an effective amount of torsemide and a pharmaceutically acceptable carrier, wherein the torsemide is torsemide modification II that does not undergo any significant rearrangement into other polymorphic forms of torsemide upon storage for at least 3 months at 40° C and 75% relative humidity.

53. (previously presented) The stable pharmaceutical formulation of claim 52 wherein the torsemide is greater than 98% torsemide modification II.

54. (previously presented) The stable pharmaceutical formulation of claim 53 wherein the torsemide is greater than 99.5% torsemide modification II.

55. (previously presented) The stable pharmaceutical formulation of claim 52, 53 or 54 wherein said pharmaceutically acceptable carrier has a low water content.

56. (previously presented) The stable pharmaceutical formulation of claim 55 wherein said carrier having a low water content is selected from lactose anhydrous, crospovidone, povidone, cellulose, and magnesium stearate.

57. (previously presented) The stable pharmaceutical formulation of claim 52, 53 or 54 wherein said formulation is a tablet.

58. (previously presented) The stable pharmaceutical formulation of claim 57 wherein the torsemide modification II is present in an amount of 2.5 to 200 mg per tablet.

59. (previously presented) The stable pharmaceutical formulation of claim 58 wherein the torsemide modification II is present in an amount of 100 mg per tablet.
60. (previously presented) The stable pharmaceutical formulation of claim 58 wherein the torsemide modification II is present in an amount of 5 mg per tablet.
61. (previously presented) The stable pharmaceutical formulation of claim 58 wherein the torsemide modification II is present in an amount of 2.5 mg per tablet.
62. (previously presented) The stable pharmaceutical formulation of claim 52, 53 or 54 wherein the torsemide modification II does not substantially rearrange into torsemide modification I.
63. (previously presented) The stable pharmaceutical formulation of claim 52, 53 or 54 wherein the torsemide modification II has a particle size distribution wherein 100% is below 200 μm .
64. (previously presented) The stable pharmaceutical formulation of claim 63 wherein the torsemide modification II has a particle size distribution wherein 100% is below 100 μm .
65. (previously presented) The stable pharmaceutical formulation of claim 64 wherein the torsemide modification II has a particle size distribution wherein 100% is below 50 μm .
66. (previously presented) The stable pharmaceutical formulation of claim 52, 53 or 54 having an *in vitro* dissolution rate, when measured by the USP Paddle Method at 50-90 RPM in 900 mL water is not less than 80% (by weight) of the torsemide modification II released after 30 minutes.
67. (previously presented) The stable pharmaceutical formulation of claim of claim 66 wherein the *in vitro* dissolution rate does not substantially change over time.
68. (previously presented) The stable pharmaceutical formulation of claim 67 wherein the *in vitro* dissolution rate does not substantially change for at least 3 months.

69. (previously presented) A method of treating edema in a patient comprising administering an effective amount of the stable pharmaceutical formulation of claim 52, 53 or 54 to the patient.

70. (previously presented) The stable pharmaceutical formulation of claim 9 wherein the torsemide modification II is selected from the group consisting of high purity torsemide modification II and torsemide modification II containing torsemide modification I at trace amounts, wherein the high purity torsemide modification II contains less than about 0.5 weight% torsemide modification I, and wherein the trace amounts of torsemide modification I is about 0.5 weight% to about 2 weight%.

71. (previously presented) The stable pharmaceutical formulation of claim 70 wherein the torsemide modification II is torsemide modification II containing torsemide modification I at trace amounts.

72. (previously presented) The stable pharmaceutical formulation of claim 9 wherein the torsemide modification II has a particle size distribution such that 100 % is below 200 μ .

73. (previously presented) The stable pharmaceutical formulation of claim 72 wherein the particle size distribution is such that 100% is below 100 μ .

74. (previously presented) The stable pharmaceutical formulation of claim 73 wherein the particle size distribution is such that 100% is below 50 μ .

75. (new) The stable pharmaceutical formulation of claim 11 wherein the torsemide modification II is high purity torsemide modification II and wherein the high purity torsemide modification II contains less than about 0.5 weight% torsemide modification I.

76. (new) The stable pharmaceutical formulation of claim 75 wherein the torsemide modification II has a particle size distribution such that 100 % is below 200 μ .

77. (new) The stable pharmaceutical formulation of claim 75 wherein the particle size distribution is such that 100% is below 100 μ .

78. (new) The stable pharmaceutical formulation of claim 75 wherein the particle size distribution is such that 100% is below 50 μ .